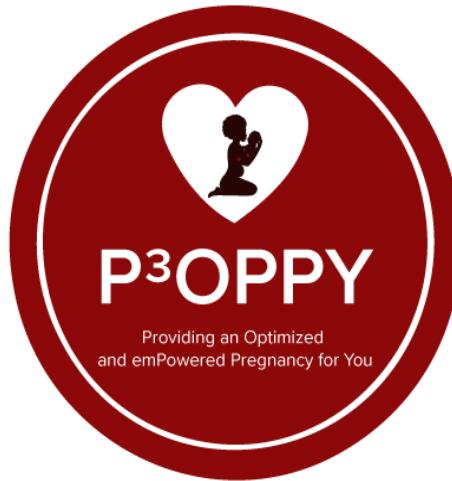

Providing an Optimized and empowered Pregnancy for You (P³OPPY)

Aim 2: Pilot



Protocol v2.0

Funded by the American Heart Association HERN 300009897 through the
P3 EQUATE Network

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1 Introduction

1.1 P3 EQUATE Overview

The P³OPPY Project is one of five projects within the P3 EQUATE Network. The overarching goal of the P3 EQUATE American Heart Association Health Equity Research Network (HERN) is to promote equity in Maternal and Infant Health outcomes by identifying innovative and cost-effective strategies to enhance access to quality health information, care, and experiences during pregnancy, postnatal and postpartum/preconception periods, particularly for Black and underserved populations. Collectively, our team will collaborate with pregnant and postpartum people and their families, hospitals, and communities to discover ways to reduce racism and social problems that contribute to poor health outcomes.

1.2 P³OPPY Overview

The purpose of the P3 Providing an Optimized and emPowered Pregnancy for You (P³OPPY) study is to evaluate promising interventions to reduce disparities and improve healthcare access and quality among pregnant women and their infants from historically marginalized communities. We will test the hypothesis that an innovative mobile-health integrated care model and/or a community health worker integrated care model will improve pregnancy outcomes among women who experience persistent disparities. POPPY has three aims: 1) Qualitative aim to understand how best to tailor the digital health and community health worker interventions (this is addressed in a separate, previously approved IRB application), 2) a pilot randomized trial (n=40) randomizing eligible patients to a digital health intervention, a community health worker intervention, or both (covered in the enclosed application), 3) a randomized trial of 400 pregnant patients to determine if digital health and/or community health workers can improve pregnancy outcomes (a future application). The enclosed protocol describes the activities of Aim 2, the pilot trial.

1.3 Study Abstract

US maternal mortality and preterm birth rates are among the highest in the developed world due, at least in part, to a combination of racial, regional and socioeconomic disparities. Our preliminary work demonstrates that differences in the Area Deprivation Index (ADI) are associated with racial/ethnic disparities in maternal and perinatal outcomes in Alabama. Patients living in resource-poor, or high ADI areas, may benefit from modifications at the patient-level to ensure equitable access to high-quality maternal care. The enclosed P³OPPY Pilot Study will determine if randomizing and implementing a digital health and/or community health worker interventions are feasible.

1.4 Pilot Study Aims

1. To assess the feasibility of the DHI and CHW interventions by assessing patient acceptance and use of the intervention.
2. To assess study enrollment to determine appropriateness and usefulness of the inclusion and exclusion criteria to estimate enrollment duration in the planned trial.
3. To determine the number of prenatal visits and the incidence of some of the maternal and neonatal outcomes (ones with higher prevalence) or surrogate outcomes that will be targeted in the planned factorial design randomized controlled trial. (Data will be collected on all relevant maternal and neonatal outcomes. The randomized feasibility design will allow for effect size estimates of the intervention on the incidence of maternal and neonatal outcomes, which will aid in determining the appropriate target outcomes as well as power calculation of the more definitive trial.)

1.5 Purpose of Study Protocol

The purpose of the P3 Providing an Optimized and empowered Pregnancy for You (P³OPPY) study is to evaluate promising interventions to reduce disparities and improve healthcare access and quality among

pregnant women and their infants from historically marginalized communities. The enclosed protocol for the pilot study will assess feasibility of randomization and implementation ahead of the planned clinical trial.

A manual of operations supplements the protocol with detailed specifications of the study procedures.

2. Background

Maternal health disparities in the United States (US) are disturbingly high — The US has the highest maternal mortality (MM) rate – 32.9 deaths per 100,000 live births – among industrialized countries, and Alabama has the third highest MM rate in the US [1,2](#). These starkly high rates are marked by persistent, unacceptable disparities. Unfavorable social determinants of health (SDoH), structural racism, and systemic barriers lead to suboptimal health outcomes in pregnant women from historically marginalized backgrounds [3,4](#). In 2020, the MM rate for Non-Hispanic White (NHW) women in the US was 19.1 deaths per 100,000 births, while the MM rate for NHB women was nearly three times higher at 55.3 deaths per 100,000 live births.¹ MM represents the “tip of the iceberg,” as each death represents numerous “near-misses” that the Centers for Disease Control and Prevention (CDC) captures in a severe maternal morbidity (SMM) composite of 21 outcomes that have profound short and long-term ramifications [5,6](#). As summarized in a review by Sinkey (P3OPPY Co-PI), NHB women are also more likely to experience each component of the CDC SMM index versus NHW women [7](#).

Our NIH-funded supplement (3UL1TR003096) on racial disparities in maternal mortality identified a significant linear relationship between increasing levels of area deprivation and increased SMM/MM ($p<0.01$)

The effect was significant in the top three (most deprived) area deprivation index (ADI) quintiles. The ADI quantifies socioeconomic conditions linked to individual health outcomes [8](#). The ADI scale ranges from 0 – 100; 0 represents abundant resources and 100 represents the most impoverished community. Alabama patients residing in high-deprivation communities, defined as the 5th highest ADI quintile (Q), had 78% greater odds of SMM/MM compared to patients living in resourced communities (defined as ADI Q1) (OR, 1.78; 95% Confidence Interval (CI), 1.22 – 2.59; $p=0.003$) (Table 1). Other factors including NHB race, age ≥ 35 years, residing in medically underserved areas and having Medicaid or Medicare insurance were also significantly associated with an increase in SMM/MM (under review for publication). Qualitative stakeholder interviews ($n=20$) conducted by our team identified several themes felt to contribute to persistent disparities in Alabama, including the legacy of racism, institutional distrust, lack of racial diversity in medical providers, poverty, lack of transportation and other needed infrastructure [9](#).

Table 1. Association Between ADI, Race, and SMM / MM Among Women Delivering at UAB Hospital 2010 – 2020

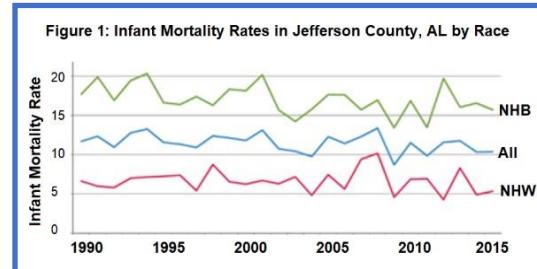
Variables	Adjusted OR* (95% CI)	P-value
Area deprivation index (quintiles)		
1 st Quintile	1.00	
2 nd Quintile	1.18 (0.95-1.47)	0.143
3 rd Quintile	1.47 (1.18-1.84)	0.001
4 th Quintile	1.55 (1.18-2.04)	0.002
5 th Quintile	1.78 (1.22-2.59)	0.003
Race		
NHW	1.00	
NHB	1.81 (1.42-2.30)	<.001
Hispanic/Latino	0.84 (0.58-1.23)	0.369

*Odds ratio and 95% confidence intervals computed using Genmod procedure with repeated subject = census block group geoid to adjust for within-subject correlation.

Inequalities in infant outcomes are equally egregious — Infant mortality rates (IMR) in the US are also among the highest in the developed world due largely to a combination of higher gestational age (GA)-specific mortality among term infants and higher rates of preterm birth (PTB) [10](#). We identified significant disparities in IMR and other adverse infant outcomes according to race [11](#) and socioeconomic status (SES) [12](#) in the US and Alabama. Alabama’s IMR was 9.3/1000 births in 2016, and despite improving to 7.0/1000 in 2018, it remains significantly above the national IMR of 5.8/1000 and among the highest in the US. Our analysis of national data showed that inter-state IMR variation is highly correlated with rates of extremely PTB ($r^2 = 0.71$; $p<0.001$) that are closely related to the proportion of births to NHB women [13](#).

In an ecological study of 6,901,328 US infants born in 2017-2018, we demonstrated that privately insured infants had a 30% lower IMR compared with Medicaid-insured infants after adjustment for race, sex, multiple births, and maternal pregnancy risk factors [14](#). Privately insured mothers had higher rates of first trimester prenatal care (PNC) (85.6% vs. 66.6%; $p<0.001$) and lower rates of infant morbidity, preterm births (PTB) and low birth weight (all $p<0.001$). Furthermore, Medicaid Enhanced PNC Programs are associated with lower IMR suggesting that interventions that enhance maternal pregnancy care improve infant outcomes [15](#).

In a recent study of 4 neonatal intensive care units by Travers (Co-I), NHB infants <29 weeks' gestation lived in areas with higher ADI percentiles than similar NHW preterm infants [16](#)[16](#). Specifically, extremely preterm infants at UAB were more likely to be NHB and had a high median ADI (81, IQR 64-92) scores. There was a significant association between ADI and mortality after adjustment for baseline characteristics. Findings from the Jefferson County, AL Health Equity Team, led by Baskin (Co-I), align with Travers' findings (Figure 1) [17](#)[17](#). SDoH including racism and SES remain important independent risk factors for adverse infant outcomes.



to

Digital health interventions (DHI) are promising channels to support improved outcomes in under-resourced communities — Though COVID-19 exacerbated the many challenges facing maternal and child healthcare delivery, it simultaneously provided opportunities to redesign the delivery of care [18](#). One such opportunity is the use of the DHI short message service (SMS) which the Cochrane Review has shown to be a promising strategy for improving maternal, newborn, and child health [19](#). Although some studies show mixed results for text-based DHI interventions in low- and middle-income countries (LMIC) and high-income countries, others targeting pregnant and postpartum (PP) women have shown these interventions improved exclusive breastfeeding, increased PNC, and increased skilled attendants at birth where a lack of skilled attendants is common [20](#). While many patients receiving texts felt supported by DHI, others cited lack of network access, internet, or phone, and literacy or privacy issues as concerns [21](#).

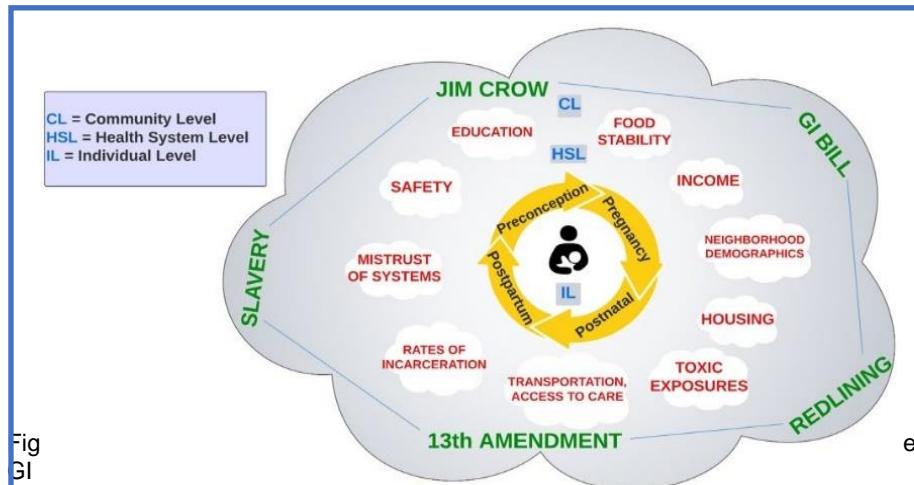
One of our EQUATE Partners, Mr. Rosin (P³OPPY Consultant), Chief Innovation Officer at Penn Medicine, in conjunction with Memora Health, developed a text-based DHI for maternal and newborn care that does not rely on a data plan or smartphone [22](#)[23](#). The DHI primarily works in two ways, 1) sending time-sensitive, culturally relevant educational texts and 2) replying to patients' texts regarding medical concerns with artificial intelligence-driven algorithms. Since smartphones nor internet access are needed for text-based solutions, this is a potentially sustainable and scalable intervention. However, DHI solutions, while helpful, may not be able to replicate the in-person face-to-face support during pregnancy and PP. Thus, CHW will also be tested in our factorial design trial.

Community health workers (CHW) comprise another promising, sustainable, and scalable strategy to improve maternal and child outcomes in under-resourced areas — There is substantial evidence supporting the effectiveness of integrating CHWs into the clinical care team [24](#)[24](#). A 2022 systematic review investigating CHW interventions and maternal/child health concluded that CHW improved pregnancy and infant health knowledge, increased PNC, and reduced IMR in LMIC [25](#). CHWs are also known to both increase access to services and improve the quality of culturally competent care. In fact, the Community Preventive Services Task Force recommends using CHW based on multiple studies demonstrating reductions in health disparities (particularly related to cardiovascular disease (CVD) and the cost-effectiveness of CHW use [26](#)[26](#). Despite this, there is limited data on the integration of CHW in the US as part of a strategy to reduce racial disparities in maternal/child health. Preliminary data from the Connection Health CHW Program, from which the P³OPPY CHW program will be adapted, demonstrated that pregnant patients paired with a CHW had 100% smoking cessation and 77% fewer missed PNC appointments than SES-matched pregnant patients without a CHW.

Community-based participatory research (CBPR) is a powerful strategy harnessing community partnerships at each stage of research — CBPR, an innovative research methodology that treats community members as equals in the research team [27](#), has transformative potential to improve maternal/infant health outcomes. In our previously mentioned qualitative interviews, stakeholders cited distrust of the medical system as a contributing factor in racial disparities in maternal death. The P³OPPY

Project provides an opportunity to mitigate this distrust through meaningful partnership. Our team (Baskin, Co-I and Scarinci, EQUATE Core) has extensive expertise in CBPR in the Deep South and other resource limited settings [28-30](#).

A properly designed randomized controlled trial (RCT) grounded in a CBPR framework³¹ is urgently needed to investigate promising DHI and CHW interventions to reduce the disparities outlined above. As shown in Figure 2, our conceptual model identifies multi-level contributors to racial disparities in maternal/infant outcomes. Each of the two P3OPPY interventions has the potential to target various disparities in the EQUATE conceptual model. The proposed aims align with the overarching goal of the American Heart Association Health Equity Research Network on Disparities in Maternal-Infant Outcomes to “aggressively address SDoH while working to improve health equity for all communities.”



3. Preliminary Data from Qualitative Interviews from AIM 1

What follows in this section 3 is a brief summary of recommendations from our one-on-one semi-structured virtual interviews from Aim 1 occurring from November 2022 – January 2023 from community leaders and maternal child health service providers for community health worker programs and digital health interventions. Note that these data are preliminary and do not include findings from ongoing interviews.

Interested parties were defined as clinical and alternative providers who provide health services to pregnant, laboring, and postpartum people and infants who identify as Black or African American in Alabama. Other interested parties were community leaders who work or volunteer with communities who primarily identify as Black or African American in Alabama. These included leaders of community-based organizations, faith-based leaders, educators, etc. outside of direct services in maternal and child health. Focus was initially on Jefferson County, but we were inclusive of perspectives outside of the county to promote feasibility in scaling up the future pilot.

Community Health Worker Intervention Recommendations:

- Characteristics of CHW:
 - Emphasize these qualities as part of recruitment, hiring interview, and screening to match clients to CHWs.
 - Seek CHWs with the following:
 - Qualities: Flexible, engaging, nonjudgmental, trustworthy, empathetic, charismatic, perceptive, approachable, respectful
 - Skills: strong listening and communication, perceptive, professional, knowledgeable, educator, advocate, proactive, resourceful
 - Demographic Characteristics: look like the participant/ relatable (i.e. mom, same race, similar background and/or from similar geographic area)
- Training for CHW:
 - Training should include: content specific to pregnancy, postpartum maternal and infant care; difficult conversations, intrinsic bias training, leadership training, art therapy, active listening, and educational program to overcome loneliness offered by UAB chaplain group.
 - Have staff listen to questions from clients about current events, new research; staff read a study and report main points to the rest of the staff.
 - Set up brief meetings with local organizations around Birmingham so the staff know the resources and exact point of contact. Have a running list and practice the “warm handoff” connection to services.
- Connecting to Moms:
 - Communicating to General Community:
 - What? Promote and inform about the role, duties, and generally who a CHW is in general and within this context.
 - Who? Communicate with local leaders (informal and formal), pregnant people, and young families.
 - Where? At existing community events (i.e. health screenings, schools, continued communication at health department, Parent Teach Organizations, or other places community members frequent.
 - Pre-Meeting: Screen centrally to match clients to CHWs based on similar characteristics when possible.
 - First Meeting:
 - Meet in-hospital or clinic.

- Have centralized screener introduce CHW to client via phone and let them decide where to meet initially. Locations: in client's home or other nearby community gathering place- church, community center, restaurant, etc.
- Other Visits: Meet where client is comfortable. Ideally the phone calls initiated by the CHW will encourage the client to initiate communication to CHW too! Over time, a relationship will be natural and meeting at home may become easier and more comfortable. Incentivize the program to encourage update. Incentives may include care items for infants (formula, clothes, diapers, etc.) and partnering with corporations may offset these expenses.
- Role and Duties:
 - Provide specific, inclusive description to clients, communities, and leaders.
 - Examples: Advocate for clients (prep client before an appointment to advocate for them self, attend appointments with them to advocate), answer questions about health, improve health literacy, remind and support in scheduling, securing childcare/ transportation for appointments, home visits for blood pressure other screenings like mental health issues; Communicate to avoid loneliness and isolation; Educate about nutrition, sleep, care for clients and infants, when to seek medical care vs. basic home care, connect to existing resources to meet all of family's needs not just direct infant and maternal health services.
- Timing/ Availability:
 - Set clear expectations during recruitment/ hiring for CHW to "meet client where they are". This should include early evenings and weekends when clients may need to talk or have questions answered.
 - CHW should set and communicate with clients their clear expectations about their availability and what constitutes an emergency vs. nonemergency.
 - Visit/ communication frequency should change over time with more frequent communication in the first 6 weeks versus more spaced out over time during the remaining months.
- Concerns:
 - Confidentiality:
 - Communicate with clients and communities about the role, duties, and benefits of CHWs.
 - Clearly describe the training they receive and what information they are expected to keep confidential (i.e. not share with others in the community).
 - Consider using the example of provider/ patient confidentiality from the medical model (HIPAA) as some may be familiar with that.
 - Communicate clearly what they are required to report vs. the purpose they are there for.
 - Safety for CHW at in-home visits
 - Hire people from similar communities.
 - Set and communicate boundaries on visiting (times, days, and expectations for reporting so other members of the household are well-informed too.)

Digital Health Interventions:

- Mode:
 - Use text messages if possible. Varied opinions on whether a text link to a secured app would be a deterrent to use.
 - Use option to "opt in" to avoid the feeling that it is invasive.
- Interventionists/ facilitators:
 - Have a live person available to respond to questions about the messages. When they need to be available will vary widely.

- Avoid having to press 1 for this and press 2 for that phone trees that may feel complicated and inhuman. Avoid “BOT” response when possible to promote tailored responses and health literacy.
 - Increase message acceptability with messages from a known person or ability to respond to a known person (like a CHW or other trusted source) rather than mass automated messages.
 - Have a person on the team who is interested in social media to be ahead of trends and increase user-friendliness.
- Frequency/ timing:
 - Preferences for when the messages should be delivered varied.
 - Frequency should change over time with more depending on the stage of pregnancy or postpartum (i.e. more in the first 6 weeks then fewer over time. Some suggested once per week then once per month.)
 - Avoid overwhelming people with too many messages (risk they will ignore).
- Content of messages:
 - Messages should extend to current events and topics of interests for clients during their stage of pregnancy, delivery, and postpartum (i.e. move beyond providing info about vitamins during pregnancy).
 - Have programmed messages with flexibility. Call upon content/ social media experts to create anticipate questions/ identify current events to develop and send messages to respond to timely questions.
- Participant Access to Phone/ Data:
 - Interventionists should be flexible and understanding regarding access. A client’s phone number may change. They may have limit on number of minutes or limited knowledge of device/ app features. They may share a phone with a member of the household. They may lack data or consistent WIFI and require going to a community place with WIFI.
 - Be proactive in communicating frequently and work with community (family, neighbors, and faith-based leaders) to track down people’s new numbers and find places nearby where they can access WIFI for free. Work with different generations in a household or community to problem solve.
- Confidentiality concerns:
 - Be aware of community concerns regarding existing programs for free/ reduced costs device or data plans. Concerns of being tracked by the government and at risk of losing their social service benefits.
 - Be aware about device/ data access issues and sharing (noted above).
 - Utilize CHW as a bridge to health system and digital health information.
 - Frame concerns around DHI confidentiality using examples from other telehealth or in-person health (i.e. CVS pharmacy script reminder to pick up, patient portal with provider’s office, are bound by HIPAA (explain HIPAA) and at risk of breach).

4. Study Design

4.1 Primary Research Objective

The P³OPPY study is designed to support the American Heart Association's mission to improve maternal/infant health outcomes and address inequities in maternal/infant health care. The promise of DHI and CHW engagement makes P³OPPY interventions potentially transformative, sustainable, and scalable for NHB mothers and their infants from underserved communities in Alabama and beyond. The objective of this pilot study is to determine if it is feasible to randomize and implement DHI and CHW interventions.

4.2 Design Summary

We will challenge existing care paradigms by testing the effectiveness of integrating innovative platforms into the existing healthcare system, including existing DHI and CHW programs from within our consortium, to eliminate critical barriers to equitable healthcare access. After seeking input from a Community Advisory Board, these interventions will be refined and deployed for pilot testing. We will specifically include NHB communities at the highest risk of adverse pregnancy outcomes and which were historically underrepresented in clinical research due to structural racism. Our cross-disciplinary collaboration effectively employs experts across the community, maternal, and infant health continuum. The use of community-based participatory research to tailor the digital health platform and optimize CHW activities/interactions represents a paradigm shift in pregnancy care. Novel technological innovations include the use of secure educational messaging and connection to local resources.

For this pilot, we will randomize a total of 40 eligible participants, 10 to usual care, 10 to DHI, 10 to CHW, and 10 to DHI + CHW

4.3 Eligibility Criteria:

Inclusion Criteria:

- Self Identifies as NHB
- Between 16-49 years old
- 8⁰ - 22⁶ weeks gestational age with a live fetus
- Dating sonogram at <23 weeks gestation
- ADI National 4th or 5th Quintile
- Planning to deliver at UAB Hospital
- Speaks and writes in English
- No indication for delivery at the time of enrollment
- Viable singleton or dichorionic twins

Exclusion Criteria:

- Declines Randomization
- Speaks or writes in languages other than English
- Currently incarcerated
- Fetal demise diagnosed prior to enrollment
- Known major structural chromosomal abnormalities prior to enrollment

4.4 Informed Consent Criteria

Written informed consent will be obtained from all participants. The risks, benefits and alternatives will be reviewed with the patient in detail. An informed consent form will be developed aligning with rules and regulations from the governing Institutional Review Board. A copy of the signed screening consent form will be provided to each participant. Both verbal and written informed consent will be obtained as needed; if this is not possible the patient will not be randomized.

5 Study Procedures

5.1 Overview

With feedback from qualitative interviews and ongoing partnership with the P³OPPY CAB, the DHI and CHW interventions developed in Aim 1 will be piloted in 40 pregnant NHB patients from high ADI (national quintiles 4&5) communities. The interventions will be implemented during pregnancy and will continue after birth until the infant reaches six weeks of life.

5.2 Recruitment and Randomization

All pregnant patients <23 weeks' gestation will be screened for eligibility. The screening will occur in the inpatient and outpatient settings at UAB. In the inpatient setting, patients with limited or no prenatal care frequently present to the obstetric triage unit and/or to the emergency department for pregnancy care, yet this often does not translate to routine prenatal care leading researchers to conclude that these patients are "vulnerable" and "should be considered as a public health strategy worth investigating" [32, 33](#). The OB/GYN team is consulted on all obstetric patients in the ED and obstetric triage unit and a "New OB Lab Panel" is ordered by routine. If this panel is ordered in the ED or obstetric triage unit, a page will be sent to the CWRH research team (on-site 24/7), alerting them to screen the patient for P³OPPY. Additionally, the CWRH team will screen the clinic schedules for potentially eligible prenatal patients in outpatient obstetric clinics. Potential participants will then be approached for enrollment by a trained member of the CWRH team.

The 1:1:1:1 randomization sequence will be uploaded by Dr. Szychowski, the Data Coordinating Center lead. Study team will be blinded to the randomization sequence.

5.3 Procedures to Obtain Informed Consent

Written informed consent will be obtained in person for entry into the study. Study staff will disclose the nature and potential risks of participating in the follow-up study. A common consent form template will be used for central IRB submission and adapted to institutional IRB requirements if relevant. This will comply with HIPAA Privacy Rules, and including authorization to obtain and review medical records. After the woman has had the opportunity to review the consent form and has had all questions answered to her satisfaction, she will initial and sign indicating her desire to participate.

5.4 DHI intervention Overview:

We will use a modified DHI developed by Memora Health in conjunction with EQUATE partners at UPenn [22, 23](#). All content is designed for 7th grade Flesch-Kincaid level or lower. We originally planned to utilize an SMS approach grounded by the literature [34-36](#). This approach is utilized by several major US academic centers. Unfortunately, we were informed by UAB legal that patients do not have the ability to consent to this as they interpret this as going against federal law. While we are disappointed in the result and view this as a barrier to improving outcomes for the most vulnerable, we have modified our approach to one approved by UAB legal. Memora will send a text message that has a link that the participant will launch. The educational byte is then launched in a secure browser and the link and message expire in 24 hours.

Education bytes sent by Memora have been modified by the POPPY Study team through a series of bi-directional meetings held over the last year. The participants are sent on average 2 text links per week that have anticipatory guidance during pregnancy, postpartum, and for the newborn through approximately 6 weeks of life / 6 weeks postpartum. There is a possibility you could be followed by this intervention for up to

3 months under qualifying circumstances. The qualifying circumstances are as follows: Intrauterine fetal demise (IUD) and a loss of a baby. The educational bytes are in accordance with the principles published by the American College of Obstetricians and Gynecologists (ACOG). The messages urge the participant to call the OB/GYN clinic or present to the UAB MEU if there are any concerns, and any alerts will be fielded to the POPPY email address covered by our research team during business hours. For example, in addition to the educational texts, a validated depression screen will be shared during pregnancy and postpartum. If the screen is positive, an alert will be emailed to the POPPY Email address and our team member will contact the patient and provide clinical resources. In the rare event that a participant states they are considering suicide, they are instructed to call 988 and to present to the MEU or the nearest emergency room immediately. Additionally, an email is sent to the POPPY email address and our team will follow up with the patient to ensure they sought care.

In addition to the secure educational bytes, the DHI provides appointment-scheduling reminders and the link to KidOne that offers transportation services to pregnant patients, postpartum patients and their infants. In order to provide patients accurate educational bytes, our team will sync with Memora using the secure SFTP platform as recommended by HSIS that will share validated variables such as if the patient delivers, if the patient was diagnosed with preeclampsia, and if the infant is living or deceased.

As this initiative is funded by the American Heart Association with the goal to reduce racial disparities in maternal morbidity and mortality, messages regarding common causes of death including infection, hypertension, hemorrhage, and heart failure are included.

5.5 CHW intervention Overview: The CHW intervention will be adapted from an ongoing CHW program in Jefferson County, AL called “*From Day One (FDO)*”, a comprehensive patient-centered program designed to educate and provide non-clinical, psychosocial, emotional support

Stages	Table 2: CHW Intervention*	
1 st Trimester	Baseline in-person assessment ^{II} ; Education on tobacco, drug and alcohol prevention; Diet and lifestyle education	
2 nd Trimester	Education on breastfeeding and birth control methods; Screenings on food insecurity; Diet and lifestyle education; Environmental Home Assessment	
3 rd Trimester	Host Baby Safety Showers to educate parents about infant safety, prevent childhood injuries, and infant nutrition	
	Maternal Engagement	Infant Engagement
Delivery-associated hospitalization	Follow-up within 48 hours after notification of birth; Breastfeeding support	Vaccine reminders and birth certificate completion support
Postpartum	Reminders to schedule PP visit; family planning / contraception education; PHQ.9; Home environment safety check; Home BP check for patients with HDP	Reminder to register baby for WIC and insurance; Reminder for 1 – 2 week pediatric check-up and immunizations and two months well check-up

*CHWs also engage with client bi-weekly from enrollment until the infant is three months old and is available to assist with Medicaid enrollment, coordinate transportation through Kid One Transport, access to healthy food, access to diaper banks, and is available to attend prenatal and infant visits with the participant according to the patient's wishes. ^{II}Includes vital signs, weight and medical and obstetric history; HDP = hypertensive disorders of pregnancy

to expectant mothers from the 1st trimester of pregnancy through their child's first year of life. FDO was developed and implemented by the Jefferson County Department of Health (JCDH) in collaboration with Connection Health, a non-profit organization in Jefferson County, AL that recruits, trains, and deploys CHWs to address the needs of the most vulnerable communities. CHWs receive 90 hours of rigorous training including >50 hours of in-class instruction, case studies, group work, role-plays, and 20 hours of self-study and assessments. To date, Connection Health has trained over 165 CHWs who have successfully engaged >90% of pregnant mothers enrolled in FDO. In the present study we are collaborating with Connection Health to identify and train CHWs to implement a modified FDO program as part of the CHW and CHW+DHI intervention arms. Table 2 describes the CHW interventions planned which may be modified based on qualitative feedback in Aim 1.

Based on feedback from our interviews and advisory board, participants randomized to the community health worker intervention will be connected to their CHW through the UAB Research team. The CHW will call the participant over the phone to introduce herself, and will offer to meet her at her doctor's appointment (if she desires) or virtually based on the patient's preference. The CHW will reach out to the participant every other week and specific activities are outlined in the enclosed table. Over time, a relationship will develop and it is our goal that the CHW will be seen by the participant as an advocate to navigate the healthcare system.

In other research studies in conjunction with UAB, ConnectionHealth has entered into an IRB Authorization Agreement whereby the UAB IRB is the IRB of record for ConnectionHealth. We plan to use this same IRB structure for the POPPY Study.

5.4 Virtual Visits (for CHW) if applicable

If needed, the CHW will initiate a virtual visit in place of an in-person visit upon request by the participant. Virtual visits can be conducted by phone, video chat applications, computer-based programs (i.e. Zoom, Microsoft Teams, WebEx), or other platform that the site or participant prefers. During the virtual visits, baseline and home assessments, questionnaire will be asked of the participant, educational information and reminders will be given. We will ask about any new diagnoses or medications.

5.5 In-person Visit / Procedures

Here is the summary of the assessment visit across the enrollment

	Enrollment	28 – 32 weeks	Delivery Discharge / Neo Discharge	Postpartum Visit
Screening and Randomization Form	X			
Baseline Data Form including:	X			
Demographics	X			
Medical history	X			
Food insecurity	X			
Housing stability	X			
Social support	X			
Neighborhood / social environment	X			
Perceived Healthcare Access	X			
Everyday discrimination scale	X	X	X	X
Experience of discrimination	X	X	X	X
PHQ-9	X	X	X	X
Perceived Stress Scale	X	X	X	X
MORI Form	X	X	X	X
Prenatal course, breastfeeding plans		X		
Health literacy		X		
L & D Form (include prenatal course/complications)			X	
Miscarriage or early termination form	X			
Neonatal Form			X	
NICU Form			X	
Maternal Postpartum Follow up				X
Neonatal Readmission				X
Neonatal Well Being (combine with readmission?)				X
Intervention satisfaction form				X
SAE Form	X	X	X	X

Protocol Violation Form	X	X	X	X
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***Items in **blue** denote common data elements across the EQUATE Network endorsed by the Social Determinants of Health Core

Medical history and questionnaire administration will be completed by site investigator or a trained delegate. Patients will be encouraged to have all medication present. In addition, participants will be asked to sign a medical record release so that medical records can be obtained and reviewed by the study team if not previously done.

5.6 Adverse Event Reporting

Detailed information concerning relevant adverse events will be collected and evaluated throughout the conduct of the protocol. Many of these including death, CVD morbidities, and hospitalizations will be collected as study outcomes. An Adverse Event Form will only be completed for any event that is not already being collected as an outcome that is serious, deemed related to the study, and/or unexpected in nature, severity or frequency. The Adverse Event form will be submitted within 7 days of becoming aware of Adverse Event.

5.7 ADAPT-ITT: The ADAPT-ITT framework ³⁷ will be used to adapt P³OPPY DHI and CHW interventions to make it culturally relevant to NHB women in low-resourced communities in Alabama.

6. SAMPLE SIZE

6.1 A convenience sample of 40 pregnant NHB patients from high ADI (national quintiles 4&5) communities will be randomized in the P³OPPY pilot.

N= 40: Usual care (n=10), DHI alone (n=10), CHW alone (n=10), CHW+DHI (n=10)

7. DATA COLLECTION

7.1 (eDES) Electronic Data Entry System

Maternal/perinatal variables will be directly entered into the eDES database by trained CWRH staff. All data will be stored in UAB eDES on case report forms piloted by the P³OPPY study team and the EQUATE Data Management Core Staff.

7.2 Data collection forms

Detailed data collection forms will be included in an accompanying manual of procedures.

8. STUDY ADMINISTRATION

8.1 Organization and Funding

The study is funded by the American Heart Association (AHA). A complete description and listing of the participating centers is provided in the Manual of Operations.

8.2 STUDY TIMETABLE

Study Aim	Milestone	Year			
		1	2	3	4
1 – Qualitative	Finalize protocols, obtain IRB approval	Yellow			
	Conduct qualitative interviews		Yellow		
	Recruit Community Advisory Board (CAB)				
	Disseminate findings from qualitative interviews		Yellow		
	Bidirectional communication with CAB			Yellow	
2 – Pilot and Adapt	Integrate DHI into UAB Electronic Medical Record		Blue		
	Recruit and Train 2 CHW	Blue			
	Refine P ³ OPPY DHI and CHW interventions through iterative and pilot testing in 30 pregnant patients		Blue		
	Disseminate findings from P ³ OPPY DHI and CHW Pilot			Blue	
3 – Clinical Trial	Recruit and Train 10 CHW			Green	
	Participant recruitment			Green	
	Collect trial data			Green	
	Data analysis			Green	
Next Steps	Abstract & manuscript preparation and submission				Green
	Synthesize all study findings				
	Disseminate findings to community partners and at scientific meetings				Dark Purple

EQUATE Network Members are underlined.

Appendix A

P3OPPY Providing an Optimized and emPowered Pregnancy for You

Aim 2: With feedback from qualitative interviews and ongoing partnership with the P3OPPY CAB, we will assess the feasibility to randomize and implement the DHI and CHW interventions in 40 pregnant NHB patients from high ADI (national quintiles 4&5) communities.

Organization:

Clinical Centers: University of AI at Birmingham (Clinical Coordination)

Data Coordinating Center: University of AI at Birmingham Dept. of Biostatistics School of Public Health

Funding Source: The American Heart Association

Design: The purpose of the P3 Providing an Optimized and emPowered Pregnancy for You (P3OPPY) study is to evaluate promising interventions to reduce disparities and improve health care access and quality among pregnant women and their infants from historically marginalized communities. In this pilot we will assess whether it is feasible to randomize and implement DHI and CHW interventions.

Inclusion Criteria:

- Self Identifies as NHB
- Between 16-49 years old
- 8^o - 22⁶ weeks gestational age with live fetus
- Dating sonogram at <23 weeks gestation
- ADI National 4th or 5th Quintile
- Planning to deliver at UAB Hospital
- Speaks and writes in English
- No indication for delivery at time of enrollment
- Has a smartphone
- Viable singleton or dichorionic twins

Exclusion Criteria:

- Declined randomization
- Speaks or writes in language other than English
- Currently incarcerated
- Fetal demise diagnosed prior to enrollment
- Known major structural or chromosomal abnormalities prior to enrollment

Sample Size: 40 Non-Hispanic Black Women

Aim: To assess the feasibility of randomizing and implementing the DHI and CHW interventions in 40 NHB pregnant women from high ADI communities.

Measures: SDOH Measures as per EQUATE SDOH Core, Perceived stress scales PHQ-9 and Mother on respect index (MORI)

Appendix B – Abstract submitted to the American Public Health Association Meeting resulting from Aim 1 data

Community and provider perspectives on community health worker strategies to reduce maternal health inequities in Alabama

Molly Richardson, PhD, MPH¹, Angelina Toluhi, MD, MPH¹, Rosylen Quinney², Donna Dunn², Henna Budhwani, PhD, MPH³, Vivek Shukla, MD², Alan Tita, MD², Colm Travers, MD², Martha Wingate, DrPH, MPH¹, Brian Casey, MD², Trinita Ashford⁴, Lynetta West⁴, Kayla Torres⁴, Waldemar Carlo, MD², Rachel Sinkey, MD² and Janet Turan, PhD, MPH¹

Abstract:

Objective: Despite ongoing efforts to reduce inequities in maternal mortality, Alabama has the third worst maternal mortality ratio in the United States. We aimed to identify community and provider perspectives to inform the development of a community health worker (CHW) program to reduce adverse pregnancy outcomes among non-Hispanic Black (NHB) pregnant women in Alabama.

Methods: We purposively recruited key informants who work with NHB populations in historically underserved locations in Alabama. A semi-structured interview guide was informed by Andersen's Behavioral Model of Healthcare and revised with the help of a community advisory board (CAB). Twenty in-depth interviews were conducted virtually. Rapid qualitative analysis approaches were used to identify recommendations for CHW interventions.

Results: Participants included maternal health providers (n=10, clinicians, doulas, lactation consultants, social workers) and community leaders (n=10, faith-based leaders, educators, and community-based organization representatives). Participants identified the importance of having CHWs with similar socio-demographic characteristics to clients in order to enhance relationship development. Participants also emphasized the need to clearly describe CHW's role, duties, and benefits to clients and community members. They recommended specific trainings for CHWs, providing guidelines for their safety, and talked about the need to address concerns over confidentiality. Overall, interviewees were optimistic that a CHW program could successfully reduce maternal health disparities.

Conclusions: These contextually appropriate preliminary recommendations, as well as findings from ongoing interviews with NHB patients who experienced adverse pregnancy outcomes and their family members, will be incorporated into a CHW intervention to be pilot-tested in the next phase of the study.

Appendix C – Abstract submitted to the American Public Health Association Meeting resulting from Aim 1 data

The potential for digital health interventions to improve pregnancy outcomes in historically marginalized communities in Alabama.

Angelina Toluhi, MD, MPH¹, Molly Richardson, PhD, MPH¹, Rosylen Quinney², Donna Dunn², Henna Budhwani, PhD, MPH³, Vivek Shukla, MD², Colm Travers, MD², Martha Wingate, DrPH, MPH¹, Brian Casey, MD², Roy Rosin, MBA⁴, Alan Tita, MD², Eric Wallace, MD, FASN², Waldemar Carlo, MD², Rachel Sinkey, MD² and Janet Turan, PhD, MPH¹

Abstract:

Objective

Racial disparities in maternal health outcomes persist in Alabama. Our multidisciplinary team sought to identify provider and community perspectives on the potential use of digital health interventions (DHIs) to reduce racial disparities in maternal and child health (MCH) and to inform tailored DHI interventions for Black pregnant women Alabama.

Methods

A semi-structured interview guide was developed using Andersen's Behavioral Model of Healthcare Utilization with input from a Community Advisory Board. We conducted 20 qualitative in-depth interviews with purposively selected participants including MCH providers (N=10: doulas, social workers, government agency staff) and community leaders (N=10: pastors, educators, and community-based organization representatives). Coding and analysis of transcripts using the NVivo software resulted in emergent themes.

Results

Participants identified DHIs currently available across Alabama including texting programs, mobile/computer applications, telehealth/telemedicine, and patient portals. Facilitators for DHI utilization included patient awareness and user friendliness of DHIs. Participants felt that the advantages of DHIs, including easy access to health information and improved communication with the health system, outweighed disadvantages such as lack of internet/WiFi access in some areas, cost of smartphones, or privacy issues. Participants emphasized the importance of determining the optimal timing, frequency, and content of messages in texts, as well as ensuring ease of access to patient portals and applications for local communities.

Conclusion

Results indicate that DHIs show promise for addressing maternal health needs of Black pregnant individuals in Alabama. Future MCH interventions for this population can include the development and testing of accessible and user-friendly DHIs in collaboration with local communities.

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